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Report Series

Packaging Materials: 1. Polyethylene Terephthalate (PET) for Food Packaging Applications

Report

ILSI Europe
International Life Sciences Institute

Commissioned by the ILSI Europe Packaging Materials Task Force

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International Life Sciences Institute

PACKAGING MATERIALS 1. POLYETHYLENE TEREPHTHALATE (PET) FOR FOOD PACKAGING APPLICATIONS

Updated Version

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REPORT

COMMISSIONED BY THE PACKAGING MATERIALS TASK FORCE

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1. INTRODUCTION

Polyethylene terephthalate (PET) is a plastic material that has found increasing applications within the packaging field. It is a simple long-chain polymer, and its chemical inertness together with its physical properties has made it particularly suitable for food packaging applications. The purpose of this report is to provide the salient facts about PET as a food packaging material. It describes the properties of PET with respect to its effects on the safety and health of consumers, and should be seen as an introduction to the more detailed information available, much of which is referenced herein.

2. WHAT IS PET?

PET is a long-chain polymer that belongs to the generic family of polyesters (Brody and Marsh, 1997). PET is mainly formed from the monomers terephthalic acid (TPA) or dimethyl terephthalate (DMT) both of which are derived from oil feedstock, and mono ethylene glycol (MEG) which can be derived from oil/gas feedstock or from bio-resources ("biobased MEG"). The production of bio-based TPA is currently only at the Research & Development stage. Small amounts of co-monomers such as isophthalic acid (IPA) or 1,4-cyclohexanedimethanol (CHDM) may also be incorporated into PET to enhance processing and performance. Moreover, as innovation is always in progress, it cannot be excluded that other monomers can be used after their complete risk assessment in accordance with regulatory requirements. As an example, substance diethyl [[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]phosphonate, a comonomer to enhance heat resistance of PET, received recently a positive opinion from the European Food Safety Authority (EFSA) (European Food Safety Authority, 2016a). Considering above potential chemical combinations involved, the generic term "PET" may cover a wide range of polymer structures.

PET is an amorphous glass-like material although, when processed into packaging, it is usually in a semi-crystalline form as a result of the crystallinity induced by either heat treatment or the orientation of the polymer chains. Nucleating agents may also be used to influence crystallization, particularly for application in trays that are intended for use at high temperatures.

Chemists Whinfield and Dickson, employees of the Calico Printers' Association of Manchester, are credited with the discovery of PET. It was eventually licensed to DuPont for use in the USA and to Imperial Chemical Industries (ICI) for use in the rest of the world (Dupont, 1997). Further experimental work of both DuPont and ICI chemists led to the development of PET fibres. Polyester fibre applications have further developed to such an extent that PET represents over 50% of manufactured global synthetic fibres (Albrecht, 1997).

In the late 1950s, PET was developed as a film. It was first used for video, photographic, and X-ray films, as well as in flexible packaging. PET was later modified for use in injection-molded and extruded articles, and was primarily reinforced with glass fibre. In the early 1970s, PET was stretched using blow-molding techniques that produced the first oriented three-dimensional structures. This development initiated the rapid exploitation of PET for producing lightweight, tough, unbreakable bottles (Wyeth and Roseveare, 1973 and 1974).

3. THE MANUFACTURE OF PET

Polyesters are formed by the reaction of bifunctional acids or esters and bifunctional alcohols, in the presence of a metal catalyst.

The key polymerisation step is known as a condensation reaction in which the starting materials react and release water or alcohol such as methanol. The first phase of polymerisation is generally conducted in the melt phase. After achieving an adequate degree of polymerisation, the polymer may be pelletized and the second polymerisation reaction continues in the solid phase. Technology developments in recent years have led to PET resins that can be produced in a one-step process called Melt-to-Resin (MTR) technology.

For the manufacture of PET, the key starting materials are terephthalic acid (1,4-benzene dicarboxylic acid, TPA) and mono ethylene glycol (1,2-ethanediol, MEG). When heated together, an esterification reaction occurs forming a prepolymer which contains the monomer bis-hydroxyethyl-terephthalate (BHET) and low-molecular-weight polymers (oligomers). Water formed as a by-product is removed from the process. The remaining mixture is then further polymerized, at high temperature (270-295°C) under vacuum, to form PET, while the excess ethylene glycol is distilled out (Figure 1). At this stage, the PET is a viscous, molten liquid that is extruded and water quenched into granules to form a solid, glass-like amorphous material. PET could also be manufactured by using a technology based on DMT instead of TPA. In this case, methanol is produced as by-product instead of water.

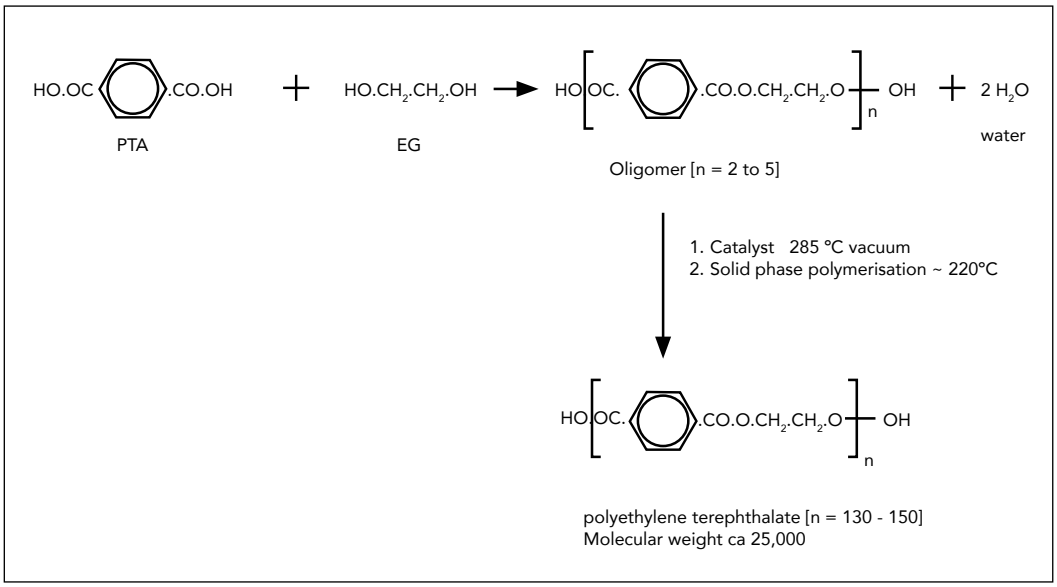
The high molecular weight required for container manufacture is obtained by a second polymerisation stage carried out in solid state after crystallization of the granules. This solid state polymerization (SSP) is conducted at lower temperatures (220-235°C) than the first polymerization in the melt phase, either under vacuum or under positive pressure using a neutral gas such as nitrogen. The reaction is driven by elimination of by-products such as water from the interior of pellets to the surface. At the same time, volatile impurities, thermal degradation products such as acetaldehyde or residual glycols are removed by thermal desorption. As such SSP process drastically limits the potential of substances to migrate to food, it makes PET a fully compatible food grade material. The high molecular weight is essential for good mechanical properties, and provides stiffness, toughness, and creep resistance, as well as sufficient strength to resist bursting and breaking under pressure.

Although most PET is produced according to the process described above, recent technologies have been developed and implemented at industrial scale to produce high-molecular-weight PET for food packaging without the solid-state polymerization step (e.g. MTR technology).

High-purity polymers are needed for food packaging applications. Once the polymer is formed, it is very difficult to purify except for the removal of volatile materials at high temperatures and under vacuum or under nitrogen flow. For this reason, the purity of the starting monomers is the key to achieve the high molecular weight and product quality required for food packaging. Vacuum distillation processes easily purify ethylene glycol; terephthalic acid is purified by repeated crystallization from solvents and as a result it is usually called Purified Terephthalic Acid (PTA).

Catalysts are used at extremely low concentrations to promote the reactions and ensure practical economics. Antimony is the currently preferred catalyst. Residual levels of the antimony in PET bottles from the EU market range from 70-290 mg/kg material with a median of 220 mg/kg material (Welle and Franz, 2011). Other metal catalysts such as Titanium, Germanium and Aluminium may also be used.

Figure 1: Chemistry of the Formation of PET (from PTA)



4. THE PHYSICAL NATURE OF PET

PET exhibits interesting physical properties (morphology). It is classified as a semi-crystalline polymer that, depending on fabrication conditions, can have a molecular structure that is amorphous or semi-crystalline. Crystallinity can be induced either by mechanical stretching or by thermal crystallization. In case of the former, by heating the polymer above 78°C (the approximate glass transition temperature Tg) it changes from a rigid glass-like state to a rubbery elastic form in which the polymeric chains can be aligned in either one direction to form fibres, or in two directions to form films and bottles. Stretching at the correct temperature and rate induces chain orientation and crystallinity. If the polymer is cooled quickly while being held in the stretched state the chains are frozen with their orientation and induced crystallinity intact. Once set in this oriented form the material is extremely tough and possesses the properties seen in a typical PET bottle. Although there is a significant amount of crystallinity in the container, it remains transparent because the crystals are very small and do not effectively scatter light in the visible region. By using a combination of specific PET grades and blowing conditions the crystallization rate of the bottle walls can be increased. The process is named 'heatset', and such bottles can withstand hot filling conditions. Thermally induced crystallization happens when amorphous PET is held at temperatures above 78°C and not quenched rapidly enough. The material becomes white, opaque, more rigid, and less flexible. A thermal crystallized PET, known as crystalline PET or CPET, contains crystallites that are much larger than those in oriented PET. In this form, it is capable of withstanding higher temperatures without shrinkage or deformation and can be used to manufacture trays and containers that are capable of withstanding moderate oven temperatures. The careful manipulation between amorphous forms and oriented or thermally crystallized semi-crystalline forms of PET, all of which are variants of the same basic chemical formula of PET, permits its use in a wide range of products.

The PET described thus far is the simplest typical product. However, several modifications may be introduced to develop specific properties for various packaging applications and to suit particular manufacturing equipment. The modifications are generally of a chemical nature that facilitates manipulation of the PET between different crystalline forms.

For example, small concentrations of an appropriate co-monomer (e.g. IPA or CHDM) slow the speed of crystallization. This property is especially important for the heavier, thicker articles like the bottles that are used for refillable container systems (e.g. 5 Gallon water containers) for which application-specific resins with higher co-monomer content have been developed. Influencing the rate of crystallization and the crystal morphology to restrict movement and container deformation is also required for articles used at elevated temperatures, such as ovenable food trays. For crystalline PET (CPET) tray applications, a nucleating agent or crystallization promoter and a higher-molecular-weight polymer are used. Impact modifiers are also often added to CPET trays to reduce the potential for breakage should a frozen food be dropped onto a hard surface.

PET has become a packaging material for many food products, particularly beverages. Being an inert material with good physical properties and glass-like transparency makes PET a good option for water packaging. Other reasons for its frequent use as food packaging material are its good gas barrier properties and retention of carbonation during the normal distribution and usage of carbonated beverages. PET also exhibits a high toughness/weight property ratio that enables the manufacture of lightweight, large-capacity and almost unbreakable containers.

5. FOOD PACKAGING APPLICATIONS

The necessary and desired properties for packaging applications are attained from the intrinsic properties of the PET polymer. Nevertheless, as PET is a polyester, molecular chains will hydrolyse during processing at high temperature if moisture is present and therefore, PET has to be dried prior to processing. Additives such as antioxidants, plasticizers, and heat or ultraviolet (UV) stabilizers are in general not used in PET. To produce coloured packaging, colorants in low concentrations (usually less than 500 ppm) are generally added at either the resin or the container manufacturing stage.

Nevertheless, some additives may be used to meet the needs of specific applications. For example, UV absorbers may be used for packaging foods that are sensitive to UV light (Monteiro *et al*, 1996 and 1999); reheat additives may be used to improve the efficiency of the bottle-blowing process; and others may be used to reduce friction in filling lines. For some demanding applications, acetaldehyde scavengers may be incorporated to reduce the migration of acetaldehyde, or oxygen scavengers may be used for packaging foods or beverages that are particularly sensitive to oxygen. CPET trays may also include nucleating agents, antioxidants, impact modifiers, and mold release agents.

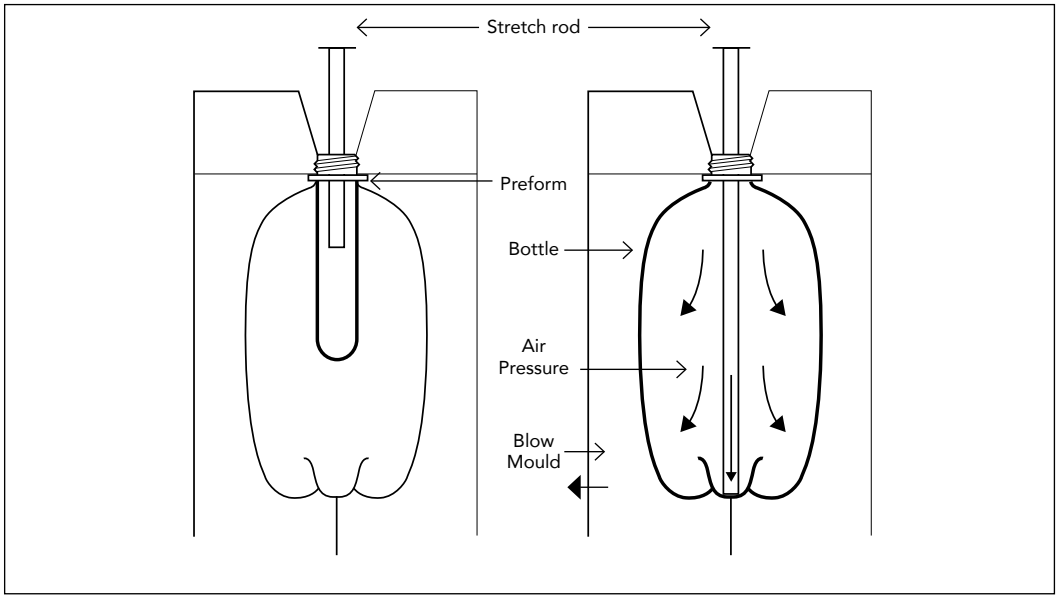
The three major packaging applications of PET are containers like bottles, jars, and tubs, semi-rigid sheets for thermoformed trays and blisters, and thin oriented films used for bags and snack-food wrappers (Table 1).

Table 1: PET in Food Applications

Technology	PET product	Applications
Injection Stretch Blow Molding	Bottles	Beverages, fruit juices, bottled waters, and alcoholic beverages; especially suitable for carbonated drinks, cooking and salad oils, sauces and dressings Beer – wine –
	Wide-mouth jars and tubs	Jams, preserves, fruits, and dried foods Condiments, coffee
Thermoforming	Trays (CPET)	precooked meals for reheating pasta dishes, meats, and vegetables in either microwave or conventional ovens vacuum-packed dairy products (cheese), processed meats
	Trays (APET)	deli trays, used at room temperature or below
Films	Films and metallized foils	Boil-in-bag precooked meals, snack foods, nuts, sweets, long-life confectionery, ice creams, and spreads

PET bottles and jars are manufactured by the process of injection stretch blow molding, which was developed specifically to maximize PET's beneficial properties (Figure 2). Selecting the preform design together with appropriate blowing parameters will help to achieve the best balance of properties. Impact resistance, transparency, stiffness, gas barrier properties, and resistance to creep are all optimized during this stage of bottle manufacture.

Figure 2: Stretch Blow Molding of a PET Bottle



The semi-rigid transparent PET sheet, the precursor for thermoforming PET articles such as trays, is made by extruding a ribbon of molten PET polymer onto a series of cooling and compressing rolls. The cooled sheet is then stored before it is fed through a thermoforming line that heats the sheet, stamps the forms, and cuts out the article, all in one process. Transparent PET trays that are made in this manner from amorphous PET are often referred to as APET trays. CPET trays for use

at high temperatures in microwave and conventional ovens are made starting from crystallized PET. Additives and processing techniques are used to induce and control crystallinity and to improve impact properties and thermal stability.

The manufacture of thin, biaxially-oriented PET films is a demanding operation that fully develops the properties of the PET. The excellent thermal properties of PET film allow it to be processed and used over a wider temperature range (-70°C to +150°C) than most of the common packaging films. Oriented PET films can be used in the demanding sterilization processes that are based on steam, ethylene oxide, or radiation. Again, the key to achieving these properties is manipulation between the different crystallization states. Biaxially-oriented PET films may also be metallized to additionally enhance their barrier properties and appearance.

PET can be combined with other plastics to extend its applications (e.g., provide additional protection against oxygen and moisture) by using co-injection, co-extrusion, laminating, or coating technologies.

6. FOOD PACKAGING LEGISLATION FOR PET

In general, the main purpose of each authority of a jurisdiction/country is to establish a regulatory framework and maintain/enforce regulations, including food contact material regulations, to ensure food consumed and sold within their countries is safe (Magnuson *et al*, 2013). Although there are many similarities in these regulatory frameworks, each jurisdiction has its own regulatory schemes by which plastic materials and articles are approved for use in food contact (LeNoir, 2015).

European Union

General principles of safety and inertness for all food contact materials are set out in the Framework Regulation (EC) No 1935/2004 (European Commission, 2015). The regulation states that "any material or article intended to come into contact directly or indirectly with food must be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties." GMP (Good Manufacturing Practice) Regulation (EC) No 2023/2006 ensures that the manufacturing process is well controlled so that the specifications for food contact materials remain in conformity with the legislation.

In addition to the general legislation, plastic materials and articles intended to come into contact with food are covered by a specific EU measure, Regulation (EU) No 10/2011 (and subsequent amendments) (European Commission, 2011).

The Regulation deals with three major principles:

a) the establishment of positive lists of authorized substances including monomers or other starting substances and additives;

b) an overall migration limit (OML) for the sum of all substances into the foodstuff to ensure the overall quality of the plastic; and

c) where necessary to ensure the safety, specific migration limits (SMLs) or other limitations for individual substances.

This means that for a polymer to be lawfully used, the component monomers and additives must be on the positive lists and the finished article must comply with all the applicable limitations. Some substances are exempted of listing providing they follow national laws (e.g. colorants, aids to polymerization). The regulation sets out detailed migration testing rules for testing for both OML and SMLs. Although migration testing in food prevails, migration is usually tested using simulants, representative for a food category. Food simulants defined in the Regulation are 10%, 20% or 50% ethanol, 3% acetic acid, Tenax and vegetable oil. The migration testing is done under standardized time/temperature conditions, representative for a certain food use (European Commission, 2016).

The OML for all food contact articles is 10 mg/dm2 of food contact surface.

SMLs that have been established for some of the monomers and additives used in making PET (Table 2) are based on the safety evaluation of the substances by EFSA or, in the past, by the EC Scientific Committee on Food (SCF), taking into account information on the toxicity and the migration behaviour of the substance (see point 8). For setting the SML, it is conventionally assumed that 1kg of food containing the substance is consumed daily by a person with 60 kg bodyweight. It is assumed that the 1 kg of food is in contact with a plastic food contact material releasing the substance at a level lower than the SML. It is further assumed that the food contact surface area is 6 dm2 per kg food (European Commission, 2014). Such food exposure scenario (1 kg / 60 kg person) is under discussion by EFSA and will be potentially updated in the future. The main development is in a new set of tiered approaches to stick closer with the wide range of consumer food exposures (European Food Safety Authority, 2016b).

Table 2: Some of the Monomers/Starting Substances and Additives Used in Making PET for Food Packaging

Monomers/starting substances and additives	**Specific Migration Limit (SML)**
Terephthalic acid (PTA)	7.5 mg/kg
Terephthalic acid, dimethyl ester (DMT)	No SML
Isophthalic acid (IPA)	5 mg/kg
Ethylene glycol (EG)	30 mg/kg (Alone or with diethylene glycol or stearic acid esters of ethylene glycol)
Diethylene glycol (DEG)	30 mg/kg (Alone or with ethylene glycol or stearic acid esters of ethylene glycol)
1,4-Bis(hydroxymethyl)cyclohexane (CHDM)	No SML
Antimony trioxide	0.04 mg/kg, expressed as antimony

Practically, if the product complies with the compositional requirements of the Regulation (EU) No 10/2011 (i.e., it is produced from authorized monomers and additives), then it may be tested for compliance with applicable migration limits for any desired condition of use.

It is important to note that compliance with the respective migration limits has to be ensured for the finished article although the compliance work should be concluded as high up in the manufacturing

chain as possible (European Commission, 2013). As migration testing is time consuming, costly and may be complex, it is accepted to demonstrate compliance by worst case calculation or modelling (cf. Regulation (EU) No 10/2011, Annex V, chap 2, paragraph 2.2.3).

In addition to the above, substance categories not included in the European Union positive list of authorized substances, like aids to polymerization, could be regulated at Member State level.

Apart from the three major principles, the Plastics Regulation (EU) No 10/2011 includes requirements for non-intentionally added substances (NIAS). NIAS can be an impurity in the substances used or a reaction intermediate formed during the production process or a decomposition or reaction product. Any potential health risk in the final material or article arising from reaction and degradation products should be assessed by the manufacturer in accordance with internationally recognised scientific principles on risk assessment. Guidance on best practices on the risk assessment of NIAS in food contact materials and articles can be found in another ILSI Europe Report (Koster *et al*, 2015).

United States

The U.S. Food and Drug Administration's (US FDA) regulations for food contact substances are based on the principle that food packaging must not adulterate the food, which means that any substances that migrate into food from packaging must not exceed safe levels and must not cause an unacceptable change in the organoleptic properties of the food. For a polymer to be cleared by the US FDA for use as a packaging material, a packaging-component supplier must submit data on the composition of the material, manufacturing process, physical properties, intended applications and conditions of use, studies on the migration from the material, and toxicity data for the substances that have been found to migrate. There are 3 possible routes to have a new food contact substance cleared (LeNoir, 2015; US FDA, 2015):

- The Food Additive Petition (FAP) process. A FAP approval results in a new regulation as part of the Code of Federal Regulations (CFRs). PET polymer regulation is under 21 CFR 177.1315 and 21 CFR 177.1630;

- The Food Contact Notification (FCN) process. After it is reviewed and accepted by the US FDA, the FCN is added to the list of effective notifications that the agency publishes. The notifications that are currently in effect are accessible on a dedicated web page. For PET, a notification can be found under FCN 85 (US FDA, 2000).

- The Threshold of Regulation (ToR) rule. A substance used in a food contact article may be exempted by US FDA from the need of an FCN or FAP as a food additive if the use in question has been shown to result in a very low concentration (0.5 ppb).

The CFRs or FCNs specify the compositional requirements and simple compliance tests with which the finished food contact article must comply.

Any additive that is reasonably expected to become a component of food must be used in compliance with an applicable regulation or FCN unless there is a basis for exemption, such as GRAS (generally recognized as safe) status, or if it can be demonstrated that it does not become a component of food. It is possible that the incorporation of an additive may introduce additional regulatory restrictions on the use of the polymer.

7. MIGRATION OF PET COMPONENTS

The official European methods for migration testing stipulate the use of food simulants that are intended to represent all food types. These simulants include 10% ethanol, 3% acetic acid, 20% ethanol, 50% ethanol, vegetable oil and poly(2,6-diphenyl-p-phenylene oxide) (so-called Tenax) and are generally assigned to certain food groups or specifically to different food categories. They also stipulate migration testing times and temperatures that represent the worst of the foreseeable conditions of intended use, such as 10 days at 40ºC for OML testing and 10 days at 60°C for SML testing. The US FDA has similar testing recommendations for the evaluation of migration of new polymers or additives. The US FDA also specifies a different set of compliance extraction tests for PET articles that are already regulated in 21 CFR 177.1630 and 21 CFR 177.1315. The extraction solvents include water, 3% acetic acid, heptane, 50% ethanol and 95% ethanol, depending on the intended application. PET manufacturers and container producers have been applying these tests for many years. The evaluation of new processes, materials, additives, and applications as they have arisen has generated large amounts of data. Extensive testing has shown that, although the amount of migration that occurs in a given test logically varies as a function of time and temperature of contact and the particular food or food stimulant, the migration results are well within the limits established by the regulations.

The high inertness of PET leads to very low interactions and mass transfer between PET packaging and foodstuffs (Welle, 2014). The total migration during long-term storage of PET is typically less than 0.5 mg/kg for the most common uses in bottles in contact with water (Störmer *et al*, 2004). Higher levels of migration can be seen when using the more severe test protocols such as those that are intended to simulate cooking. However, these test protocols include testing for 2 hours in contact with oil at very high temperatures, conditions that highly exaggerate those that are typically used for reheating foods (which more closely resemble a hot fill application) or for less severe cooking applications such as baking.

Specific migration of PET (co)-monomers like PTA, IPA and DMT is negligible under storage conditions and the European SML for EG cannot be exceeded under normal storage conditions (Welle, 2014).

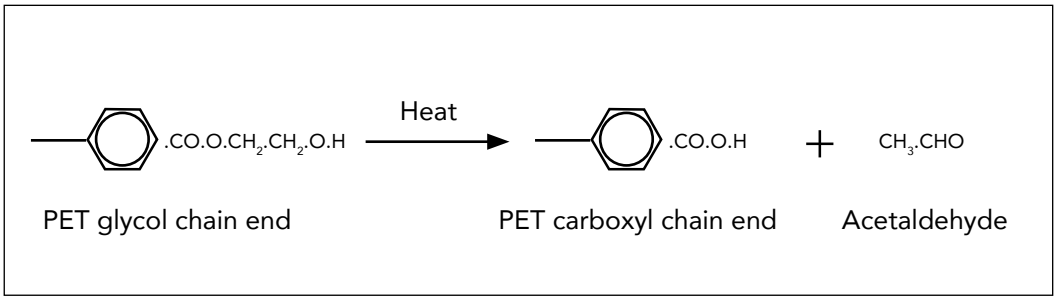
Studies designed to detect migration of antimony catalysts have shown only trace levels of antimony in the most common applications (Welle and Franz, 2011). For example, in a 2005 study of the Swiss Food Agency Bundesamt für Gesundheit (BAG, 2005) an average antimony level of 0.43 µg/L in 49 natural mineral waters packaged in PET was found, compared to approximately 0.12 µg/L in 20 natural mineral waters packaged in glass. These levels are well within the levels that have been determined as safe according to evaluation by the World Health Organization (WHO, 2011) and well below the European limit of 5 µg/L for drinking water. If specific migration testing is performed under conditions for long term storage above 6 months at room temperature, as defined by the Regulation (EU) No 10/2011 (European Commission, 2011), antimony migration is in the range of 10 µg/L (Welle, 2014), well below the SML of 0.04 mg/L. In some very specific applications such as CPET trays used in ready-to-eat meals heated in a conventional or microwave oven, migration levels exceeding the SML have been reported (Haldimann *et al*, 2007).

As discussed in the applications section, additives are not generally required but are sometimes used for specific purposes. Although many available additives have little or no potential to migrate, it is important to evaluate the migration potential, including that of substances that may be used as carriers or solvents to introduce the additives.

Apart from (co)-monomers and additives, food contact materials may contain some NIAS like impurities of raw materials or reaction and decomposition products. NIAS in PET include acetaldehyde and formaldehyde. In addition migrants as PET oligomers can be found (Mutsuga *et al*, 2005).

Acetaldehyde (CH3CHO) is the predominant volatile product formed during thermal degradation (Villain *et al.*, 1994) (Figure 3). Acetaldehyde is only formed when the polymer is molten and results primarily from thermochemical reactions (Rieckmann and Völker, 2003). In packaged waters, typical levels of acetaldehyde migration are less than 0.1 mg/L (Darowska *et al.*, 2003; Mutsuga *et al*, 2005), which is a small fraction of the SML(T) of 6 mg/kg of food that has been established for acetaldehyde and propionic acid, vinyl ester in the Regulation (EU) No 10/2011 (European Commission, 2011). Nevertheless off-taste in waters can be found if acetaldehyde is present at a level higher than 0.02 mg/L (Haack and Ewender, 2000). Therefore, much attention is paid to measuring and controlling the level of acetaldehyde in PET food containers.

Figure 3: Acetaldehyde formation



The formation of formaldehyde as a degradation product of PET is less well understood than the formation of acetaldehyde. However, data indicate that formaldehyde, which has a toxicological profile similar to that of acetaldehyde, is typically seen at lower levels than acetaldehyde (Mutsuga *et al*, 2005). The levels of formaldehyde migration are far below the SML(T) of 15 mg/kg that has been established for formaldehyde and hexamethylenetetramine (Welle, 2014).

Oligomers are generated in the PET melt during PET polymerization and further processing. Due to the general high molecular weight of the PET oligomers, their specific migration is negligible at room temperature (Welle, 2014) but is measurable at higher temperatures. Worst case total migration of PET oligomers from PET oven trays into olive oil was 17 mg/kg and 12 mg/kg using conditions of 175°C for 120 min and 150°C for 30 min, respectively (Castle *et al*, 1990). Cyclic oligomers are common migrants from PET, both virgin and recycled PET. Their migration from PET bottles varies from ppb to ppm (Begley *et al*, 1990; Kim and Lee, 2012).

8. SAFETY OF PET AS A FOOD PACKAGING MATERIAL

Before substances are authorized for use in the production of plastic materials EFSA assesses their toxicological properties. For this, EFSA considers all toxicological data, submitted as required by the guidelines for the safety assessment of a substance (EFSA, 2002). Based on toxicity results defining a No Observable Adverse Effect Level (NOAEL, mg/kg body weight / animal) and applying a safety factor (SF) to account for the extrapolation of animal data to the human situation (usually from 100 to 1000), a the tolerable daily intake (TDI = NOAEL / SF, expressed as mg/kg body weight / human) is determined. The TDI is the daily dose that could be ingested by humans over the entire lifespan without causing an adverse effect.

When necessary on the basis of the EFSA opinion, the European Commission applies as risk management measure a restriction on the use of the substances. In most cases the restriction is a specific migration limit (SML) (see point 6 and table 2) – a limit on the quantity of the substance that may transfer from the plastic to the foodstuff. Other restrictions may include a limit on the maximum quantity (QM) in the finished materials or purity criteria.

An evaluation of the safety of any food packaging must qualitatively and quantitatively consider all substances that may migrate into food from the packaging material during use and the toxicological characteristics of those substances. Potential migrants from PET packaging include low-molecular-weight oligomers, residual raw materials, catalyst residues, and decomposition products. For certain packaging application additives such as UV inhibitors, acetaldehyde scavengers and colorants may be incorporated into the package during manufacture. Because these substances are incorporated into selected PET resins and generally are proprietary to individual resin manufacturers or package converters, they are beyond the scope of this monograph. Guidance on best practices on the risk assessment of non-intentionally added substances in food contact materials and articles can be found in another ILSI Europe Report (Koster *et al*, 2015).

PET polymer has a long history of safe consumer use that is supported by both human experience and several toxicity studies (COT, 2005a, 2005b and 2008; Ceretti *et al*, 2010; Bach *et al*, 2012 and 2013). When manufactured and used in compliance with the relevant legislation, PET food packaging does not present a health concern.

In the long history of the use of PET in food packaging, there has been only one issue of concern: the potential endocrine disruption activity. Two studies claimed that some natural mineral waters samples tested in an *in vitro* test system showed the presence of substances with a hormonal effect which were not identified more specifically (Wagner and Oehlmann, 2009 and 2011). The authors claimed that the effect was more pronounced in samples packaged in bottles made of plastic PET.

In its opinion on the first study, the German Bundesinstitüt für Gesundheit (BfR) stated that it is important that possible routes of contamination are identified and that any assessment of a health risk to consumers would require additional *in vivo* studies with robust endpoints (BfR, 2009). In addition, Franz and Welle (2009) demonstrated based on migration theoretical considerations that migration of endocrine disrupting chemicals from plastics bottles cannot be the reason for the estrogenic activity measured in the mineral water samples. For BfR, the results of the studies do not result in any need for consumers to refrain from drinking natural mineral water in PET bottles. BfR reiterated this opinion in 2011 (BfR, 2011).

A migration study (Guart *et al*, 2014) of several commercial drinking waters packaged in PET bottles demonstrated that, although some substances considered as endocrine disrupting compounds were detected, they were likely to leach from the HDPE cap. The migration values found were in all cases very low.

A literature review on this subject emphasize the need to obtain more comparable and reliable information on the effects observed in the PET-bottled drinking water before concluding that there is a potential human health risk (Bach *et al.*, 2012). Moreover, another publication showed that PET-bottled water extracts did not induce any cytotoxic, genotoxic or endocrine-disruption activity in the bioassays after exposure (Bach *et al.*, 2013).

An element that sometimes mistakenly links PET to endocrine disruption activity is the confusion with phthalate ester plasticizers or orthophthalates. The name of one of the products used to make PET, terephthalic acid, does indeed sound very much akin to phthalic acid, the material used as a starter for plasticisers, and this often leads to the mistaken belief that PET contains these plasticisers. Plasticisers are additives employed in various kinds of plastic to tailor their properties and make them "softer". With respect to the chemistry, plasticisers are small molecules, capable of moving between long polymer chains to thus make plastics softer. In contrast, PET comprises very large, so-called macromolecules. Amongst the most commonly used plasticisers, we find phthalic acid ester and adipic acid ester.

With PET, the aim is for the bottle to be stiff and rigid so that the plastic can be thinner and lighter weight and to facilitate the stacking of packs on pallets. It would, therefore, be a contradiction to use plasticisers in PET. It can be definitively stated that PET bottles are completely free from any kind of plasticiser.

9. RECYCLED PET IN FOOD CONTACT USES

Environmental impact of PET

PET is a type of plastic that is recycled easily. PCI Wood Mackenzie (2016) reported that in Europe, over 1.8 million tons of PET bottles have been collected and recycled in 2015 which means that nearly 59% of all bottles placed in the European market are collected for recycling. The prediction is that by 2020 about 2 million tonnes would be collected and recycled in Europe. The total amount, by weight, of postconsumer PET bottles collected for recycling in the United States and sold to recycling markets in 2015 was 1,797 million pounds (Napcor, 2016).

Recycled PET material can be used for a wide range of applications ranging from fibers, industrial strapping, sheet, non-food contact bottles up to food contact bottles.

Recycled PET in food contact uses

Recovered and recycled PET must comply with standards that provide a level of protection that is equivalent to the use of virgin materials. The health and safety of the consumer is of the utmost importance when considering reusing and recycling plastics, as is the case for all food contact materials.

Two particular physical properties of PET make it more suitable than other plastic materials for use as a recovered, recycled material.

The first aspect is PET's inertness. Its diffusion coefficients are at least a factor of 1000 lower than some other packaging polymers presenting lower barrier properties. Such factor is given for a molecular weight around 180 g/mol at 40°C and increases quickly in function of the molecular weight value (Dole *et al*, 2006). These diffusion properties explain why it is correspondingly more difficult for contaminants to diffuse into or out of PET (Begley and Hollifield, 1993). The barrier properties of PET can be further improved by coating processes, mainly using plasma chemical vapor deposition which have been explored and optimized at lab scale and also at industrial scale. As such, migration can be further delayed or avoided (Oliveira *et al*, 2014).

The second property is its melting point of 250°C, which allows the polymer to be heated in a solid form to remove any impurities that would reasonably be expected to migrate at the lower temperatures in which he polymer would be used in contact with food.

This property has been the basis of a number of processes that are being largely used commercially for recycling of postconsumer PET into food packaging. In addition, studies dealing with migration from recycled PET bottles (Bentayeb *et al*, 2007) showed that the migration levels of non-volatile compounds including oligomers, were well below the established limits of the European Regulation (EU) No 10/2011.

In Europe, according to the Regulation (EC) No 282/2008 and amending Regulation (EC) No 2023/2006 on recycled plastic materials intended to come into contact with foods (European Commission, 2008), recycled plastics used to manufacture materials and articles intended for food contact shall be obtained only from processes authorised by the Commission following a safety assessment performed by EFSA.

On 1 July 2008 EFSA published "Guidelines on submission of a dossier for safety evaluation by the EFSA of a recycling process to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food" (European Food Safety Authority, 2008). It gives guidance to the industry on the administrative and technical data required for the evaluation by the EFSA of the risks originating from the potential migration of substances from food contact recycled plastic materials and articles into food. These guidelines cover recycling processes for all types of plastic.

Following the publication of the guidelines, dossiers on processes producing recycled plastic for food contact uses which mainly deal with PET recycling have been submitted and are currently under evaluation.

Since 2012, EFSA has adopted more than 100 scientific opinions on the safety of processes to recycle polyethylene terephthalate (PET) for use in food contact materials. All the processes are considered not to give rise to safety concerns if operated under well-defined and controlled conditions. Once this series is completed, EFSA's opinions will inform the decisions of the European Commission and Member States regarding the authorization of the evaluated processes. After that, recycled plastics used in food packaging, food containers and other food contact materials should only be obtained from processes which have been assessed for safety by EFSA and authorized by the European Commission in respect of the use conditions defined. EFSA is therefore contributing to greater consumer protection while also supporting the wider environmental objective of waste recycling.

Pending the completion of the initial authorization phase of existing processes for which an application for authorization was submitted, national provisions in force concerning recycled plastic materials and articles and recycled plastic continue to apply in the Member States.

In the USA, the US FDA has no specific regulations on the use of recycled polymers in food contact applications. However, all food contact materials, whether virgin or recycled, must be of a suitable purity for the intended use, according to the Code of Federal Regulations 21 CFR 174.5. Research projects at the National Center for Food Safety and Technology and studies conducted by private companies in the United States have demonstrated a number of ways to clean PET sufficiently for the use of postconsumer-recycled (PCR) PET in food contact applications (Thorsheim and Armstrong, 1993; Welle, 2011). The US FDA has prepared a document that assists manufacturers of food packaging in evaluating processes for recycling plastics into food packaging (US FDA, 2006). A company interested in recycling a polymer for food contact can submit data to the US FDA for review. If the US FDA considers the documentation adequate, the agency will provide an informal advice on the suitability of the recycling process in relation to the intended uses. Copies of opinion letters that the US FDA has issued for various processes for cleaning and reusing PCR in food contact applications are available at their website (US FDA, 2016).

10. GENERAL CONCLUSIONS

PET has proven to be a food packaging material with a good combination of physical properties, safety, and organoleptic characteristics. As it can be used in many packaging forms ranging from wrapping films to bottles, it constitutes a valuable basic packaging material for a variety of foodstuffs.

General toxicity and genotoxicity studies on PET, its monomers and typical intermediates indicate that this material does not pose a threat to human health. There is a significant body of evidence demonstrating that PET shows no estrogenic activity.

The chemistry of PET is simple and its intrinsic properties do not rely on the presence of additives. It can be recycled, and this is being done on an increasing scale.

11. GLOSSARY

APET	Amorphous PET
BAG	Bundesamt für Gesundheit (CH)
BfR	Bundesinstitut für Risikobewertung (DE)
BHET	Bis-hydroxyethyl terephthalate
CFR	Code of Federal Regulations (US)
CHDM	Cyclohexane dimethanol
CPET	Crystallized PET
DMT	Dimethyl terephthalate
EC	European Commission
EFSA	European Food Safety Authority
FAP	Food Additive Petition
FCN	Food Contact Notification
GRAS	Generally Recognized As Safe
IPA	Isophthalic acid
MEG	Monoethylene glycol
MTR	Melt-To-Resin
NIAS	Non-Intentionally Added Substances
NOAEL	No Observable Adverse Effect Level
OML	Overall Migration Limit
PCR	Postconsumer recycled
PET	Polyethylene terephthalate
ppb	Parts per billion
PTA	Purified terephthalic acid
QM	Residual content
SML	Specific Migration Limit
SML(T)	Total Specific Migration Limit
SSP	Solid State Polymerization
Tg	Glass transition temperature
TDI	Tolerable Daily Intake
ToR	Threshold of Regulation
TPA	Terephthalic acid
US FDA	United States Food and Drug Administration
UV	Ultraviolet
WHO	World Health Organization

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